

# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FIL	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,373	12/27/2001		Hideji Tajima	10287.48	5376
27683	7590	12/02/2005		EXAMINER	
HAYNES A			DO, PEN	NSEE T	
901 MAIN STREET, SUITE 3100 DALLAS, TX 75202				ART UNIT	PAPER NUMBER
•				1641	

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)	
10/042,373	TAJIMA ET AL.	
Examiner	Art Unit	
Pensee T. Do	1641	

**Advisory Action** Before the Filing of an Appeal Brief --The MAILING DATE of this communication appears on the cover sheet with the correspondence address --THE REPLY FILED 14 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. 1. X The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods: a) The period for reply expires <u>3</u> months from the mailing date of the final rejection. b) The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). NOTICE OF APPEAL 2. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a). **AMENDMENTS** 3. The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because (a) They raise new issues that would require further consideration and/or search (see NOTE below); (b) They raise the issue of new matter (see NOTE below); (c) They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or (d) They present additional claims without canceling a corresponding number of finally rejected claims. NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)). 4. The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324). 5. Applicant's reply has overcome the following rejection(s): 112, 2<sup>nd</sup> paragraph. 6. 🔲 Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s). 7. X For purposes of appeal, the proposed amendment(s): a) \ will not be entered, or b) X will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended. The status of the claim(s) is (or will be) as follows: Claim(s) allowed: 24,29,30 and 32. Claim(s) objected to: Claim(s) rejected: 25,26,28 and 31, 33. Claim(s) withdrawn from consideration: \_\_\_ AFFIDAVIT OR OTHER EVIDENCE 8. The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e). 9. 🔲 The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will <u>not</u> be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1). 10. The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached. REQUEST FOR RECONSIDERATION/OTHER 11. 🔯 The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached advisory action. 12. Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper Nq(s). 13. Other: \_\_\_\_\_. LONG V. LE 11/23/26

SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

# **ADVISORY ACTION**

## Amendment Entry & Claim Status

The after-final amendment filed on September 14, 2005 has been acknowledged and entered.

Claims 22-26, 28-33 are pending.

#### Withdrawn Rejection(s)

Rejection under 112, 2<sup>nd</sup> paragraph is withdrawn herein.

Rejection under 112, 1<sup>st</sup> paragraph is withdrawn for claims 24, 29, 30, 32.

## Maintained Rejection(s)

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 28, 31, 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification fails to teach that the remote-acting bodies and the micro-substances be *independently* held in the holes, cavities, concavities or convexities in the surfaces of the carriers.

Claim Rejections - 35 U.S.C. → 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 25, 26, 28, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Forrest et al. (US 4,659,678).

Forrest et al. teach a method of immunoassay of an antigen in a liquid sample comprising mixing the antigen (micro-substance), magnetic cellulose particles (remoteacting bodies and carriers) bound to antibodies to the antigen known as the antibody reagent; the mixture is incubated for a certain amount of time; a magnetic field (remote force) is applied to separate the bound from unbound. The antibody reagent comprises of anti-FITC polyclonal antibody covalently coupled with magnetizable cellulose particles which are composites of cellulose containing black ferric(ous) oxide (Fe3O4). Magnetic field can be used to manipulate or separate the antigen-bound antibodymagnetizable cellulose particles from the unbound antibody-magnetizable particles. (See col. 3, lines 30-56; col. 8, lines 15-40). The magnetic particles of Forrest are equivalent to the carrier and the remote-acting bodies of the claimed invention. Since the claimed invention fails to exclude that the carriers and the remote-acting bodies are separate entities, the magnetic cellulose particles which are composite of cellulose containing black ferric(ous) oxide (Fe3O4) read on the claimed carrier and remoteacting bodies. The target analytes can be proteins, immunoglobulins, which include

Application/Control Number: 10/042,373 Page 4

Art Unit: 1641

antibodies. Antibiotics include antibodies. (see abstract). Prior to pouring, the carriers, the remote-acting bodies and the micro-substances are separately prepared. To start out the preparation of the magnetizable cellulose particle, the cellulose and the magnetic particles have to be prepared separately before they are mixed. Since Forrest teaches mixing the suspension after incubation, agitation must have taken place. The specification of the present invention describes that the carriers that have a plurality of holes, cavities, concavities, or convexities are made up of cellulose and Forrest teaches that magnetic particles comprises cellulose and magnetite, the cellulose in Forrest must have a plurality of holes, cavities, concavities or convexities because these carriers are made up of the same material. In Forrest, since the magnetite or remote-acting bodies are fixed to the holes, cavities, etc. of the cellulose, and the antigen/micro-substance is fixed to the magnetic particles, the antigen/micro-substance must be fixed to the holes, cavities etc. of the carrier or cellulose as well. Thus, the requirements of claims 27 and 28 are satisfied. Regarding new claim 32, wherein the agitating includes using a mechanical force, there must be some kind of mechanical force occurring during mixing since Forrest teaches mixing the suspension. Regarding claim 33, since Forrest teaches that applying a magnetic field to the magnetic cellulose particles to separate or concentrate the bound from the unbound, the magnetic particles must undergo orientation in response to the magnetic field. Therefore, it is inherent that the holes, cavities of the magnetic cellulose particles are large enough.

# Response to Arguments

Art Unit: 1641

Applicant's arguments filed September 14, 2005 have been fully considered but they are not persuasive.

Regarding the 112, 1<sup>st</sup> paragraph rejection, Applicants argue that it is an inherent characteristic that the remote-acting bodies and micro-substances are independently held in holes, cavities, concavities and convexities of the carrier because the holes, cavities, etc. of the carrier can be sized so that a mechanical force such as friction holds micro-substances or remote-acting bodies there. The holding of micro-substances and remote-acting bodies to the carrier is not dependent on some additional structure or external force.

This is not persuasive because Applicants' argument is not on point. Even it was true that the holding of micro-substances and remote-acting bodies to the carrier is not dependent on some additional structure or external force, such disclosure does not imply that the remote-acting bodies and the micro-substances are independently held in holes, cavities, etc. Therefore, the remote-acting bodies and the micro substance can be bound to each other and held in holes, cavities, etc. They are not separately attached to the carrier. The remote-acting bodies bound with the micro-substance is contained in the holes, cavities, etc. but each hole does not contain the remote-acting bodies in one spot and micro-substance in another spot of the hole.

Regarding the Forrest reference, Applicants argue that Forrest does not teach that holes, cavities, concavities, convexities in a carrier could be specifically sized so as to be capable of holding micro-substance and remote-acting bodies. As to remote-acting bodies, Forrest does not teach exactly how his remote-acting bodies are held to

Application/Control Number: 10/042,373 Page 6

Art Unit: 1641

the cellulose carriers and more specifically, lacks any teaching that his cellulose carriers have holes, cavities, concavities, or convexities that are specifically sized to facilitate holding of the remote-acting bodies or micro-substance.

As discussed in the rejection, since Forrest uses cellulose as a carrier and the present invention also use cellulose as the carrier, and that the cellulose carrier in Forrest is able to hold the magnetic particles, the holes, concavities, convexities and cavities are an inherent characteristics that the cellulose in Forrest must possess in order to hold the magnetic particles/remote-acting bodies. Since the cellulose carrier is able to hold the remote-acting bodies, it must have size that fits the remote-acting bodies. The micro-substance binds to the magnetic particles, and thus are contained in the cellulose carrier as well.

#### Allowable Subject Matter

Claims 24, 29, 30, 32 are allowable.

Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do Patent Examiner November 22, 2005

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/28/06